Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0932661	07/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lanier Dermatology & Skin Cancer Specialists, Pc	605 South Enota Dr, Gainesville, GA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	On August 26, 2019, an off site followup review was completed. The report revealed that corrective action was found to be completed or acceptable progress made on the deficiencies cited. All deficiencies have been corrected. The facility is in compliance with with all regulations surveyed.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: A review of the procedure manual and an interview with the clinic administrator, it was determined that the laboratory failed to have a comprehensive competency assessment policy specific to the specialty of Histopathology from September 2017 to July 2019. Findings include: 1.) Testing Personnel(TP) records review revealed competency assessment was performed on (TP), but was not specific to Histopathology (Mohs and KOH) proccesses from September 2017 to July 2019. 2.) The clinic administrator confirmed on July 11, 2019 at approximately 12:50 pm in the break room that the laboratory failed to have competency assessment specific to Histopathology.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on the peer review documents and an interview with the clinic administrator, the laboratory failed to proof that KOH peer reviews were done at least twice a year in 2018 and 2019. Findings include: 1.) Peer review documents revealed KOH preps for mycology were not performed in 2018 and 2019. 2.) The clinic administrator in the break room at approximately 12:55 pm on July 11, 2019 confirmed the laboratory had no proof KOH peer reviews were done twice annually in 2018 and 2019.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: A review of the procedure manual and an interview with the clinic administrator, the laboratory failed to have a Quality Assurance (QA) policy specific to the specialty of Histopathology in 2018 and 2019. Findings include: 1.) Procedure manual review revealed the clinic has no (QA) policy specific to the specialty of Histopathology in 2018 and 2019. 2.) An interview with the clinic administrator at approximately at 13: 05 pm on July 11, 2019 in the break room confirmed the clinic had no written QA policy specific to Histopathology in 2018 and 2019.